



# **HIPAA SECURITY REGULATIONS EXTRACT OF PREEMPTION REFERENCES**

**45 CFR Parts 160, 162, and 164  
Health Insurance Reform: Security  
Standards; Final Rule  
(68 Fed.Reg. 8334 *et seq.* (Feb. 20, 2003))**

Prepared by:  
Stephen A. Stuart, Senior Staff Counsel  
California Office of HIPAA Implementation

**August 11, 2003**

## **EXPLANATION**

The following document is a tool designed to assist HIPAA-covered entities and persons in analyzing provisions of State law for preemption by the Health Insurance Portability and Accountability Act (HIPAA). The document is an extract of all references to HIPAA preemption of State law set forth in the Health Insurance Reform: Security Standards; Final Rule (68 Fed.Reg. 8334 et seq. (Feb. 20, 2003)). [NOYE: There are no preemption references in the Security and Electronic Signature Standards; Proposed Rule (63 Fed.Reg. 43242 et seq. (Aug. 12, 1998))]

Please forward any comments, corrections, etc. to the attention of:

Stephen A. Stuart  
Senior Staff Counsel  
California Office of HIPAA Implementation  
1600 Ninth Street, Room 460  
Sacramento, CA 95814  
sstuart1@ohi.ca.gov

**HIPAA Security Regulations**  
**Extract of Preemption References**  
**(68 Fed.Reg. 8334 et seq. (Feb. 20, 2003))**

**III. Analysis of, and Responses to, Public Comments on the Proposed Rule**

...

*G. Technical Safeguards (§ 164.312)*

...

**2. Audit Controls (§ 164.312(b))**

...

c. *Comment:* One commenter was concerned about the interplay of State and Federal requirements for auditing of privacy data and requested additional guidance on the interplay of privacy rights, laws, and the expectation for audits under the rule.

*Response:* In general, the security standards will supercede any contrary provision of State law. Security standards in this final rule establish a minimum level of security that covered entities must meet. We note that covered entities may be required by other Federal law to adhere to additional, or more stringent security measures. Section 1178(a)(2) of the statute provides several exceptions to this general rule. With regard to protected health information, the preemption of State laws and the relationship of the Privacy Rule to other Federal laws is discussed in the Privacy Rule beginning at 65 FR 82480; the preemption provisions of the rule are set out at 45 CFR part 160, subpart B....[8355 Federal Register / Vol. 68, No. 34 / Thursday, February 20, 2003 / Rules and Regulations]

...

*L. Miscellaneous Issues*

**1. Preemption**

The statute requires generally that the security standards supersede contrary provisions of State law including State law requiring medical or health plan records to be maintained or transmitted in written rather than electronic formats. The statute provides certain exceptions to the general rule; section 1178(a)(2) of the Act identifies conditions under which an exception applies. The proposed rule did not provide for a process for making exception determinations; rather, a

process was proposed in the privacy rulemaking and was adopted with the Privacy Rule (see part 160, subpart B). This process applies to exception determinations for all of the Administrative Simplification rules, including this rule.

a. *Comment:* Several commenters stated that the proposed rule does not include substantive protections for the privacy rights of patients' electronic medical records, while the rule attempts to preempt State privacy laws with respect to these records. Comments stated that, by omitting a clarification of State privacy law applicability, the proposed rule creates confusion. They believe that the rule must contain [8363 Federal Register / Vol. 68, No. 34 / Thursday, February 20, 2003 / Rules and Regulations] express and specific exemptions of State laws with respect to medical privacy.

*Response:* The Privacy Rule establishes standards for the rights of patients in regard to the privacy of their medical records and for the allowable uses and disclosures of protected health information. The identified concerns were discussed in the Privacy Rule (see 65 FR 82587 through 82588). The security standards do not specifically address privacy but will safeguard electronic protected health information against unauthorized access or modification.

b. *Comment:* One commenter asked how these regulations relate to confidentiality laws, which vary from State to State.

*Response:* It is difficult to respond to this question in the abstract without the benefit of reference to a specific State statute. However, in general, these security standards will preempt contrary State laws. Per section 1178(a)(2) of the Act, this general rule would not hold if the Secretary determines that a contrary provision of State law is necessary for certain identified purposes to prevent fraud and abuse; to ensure appropriate State regulation of insurance and health plans; for State reporting on health care delivery costs; or if it addresses controlled substances. See 45 CFR part 160 subpart B. In such case, the contrary provision of State law would preempt a Federal provision of these security standards. State laws that are related but not contrary to this final rule, will not be affected. Section 1178 of the Act also limits the preemptive effect of the Federal requirements on certain State laws other than where the Secretary makes certain determinations. Section 1178(b) of the Act provides that State laws for reporting of disease and other conditions and for public health surveillance, investigation, or intervention are not invalidated or limited by the Administrative Simplification rules. Section 1178(c) of the Act provides that the Federal requirements do not limit States' abilities to require that health plans report or provide access to certain information.

c. *Comment:* Several commenters stated that allowing State law to establish additional security restrictions conflicts with the purpose of the Federal rule and/or would make implementation very difficult. One commenter asked for clarification as to whether additional requirements tighter than the requirements outlined in the proposed rule may be imposed.

*Response:* The general rule is that the security standards in this final rule supersede contrary State law. Only where the Secretary has granted an exception under section 1178(a)(2)(A) of the Act, or in situations under section 1178(b) or (c) of the Act, will the general rule not hold true. Covered entities may be required to adhere to stricter State imposed security measures that are not contrary to this final rule....